PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
Gary Karlin Michelson, M.D.)
Serial No.: 08/354,450) Group Art Unit: 3764
Filed: December 12, 1994) Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC)
MENISCAL REPAIR)

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Sir:

APPEAL BRIEF

Real Party in Interest

The real party in interest is Gary Karlin Michelson, M.D. (hereinafter, the "Appellant").

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 1-28 have been cancelled.

Claims 29-300 are pending.

Claims 29-300 have been rejected and are being appealed.

Status of Amendments

An amendment under 37 C.F.R. § 1.116 dated September 20, 2004 (the "September 2004 Amendment") was entered by the Examiner in the Advisory Action dated November 4, 2004 (the "November 2004 Advisory Action").

Summary of Claimed Subject Matter

Independent claim 29.

The present invention in one preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together and preventing movement of rivet 100 in the tissue. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to the mid-longitudinal axis (Fig. 5), a truncated conical penetration head 114 (Specification, page 7, lines 1 and 2; Fig. 5) at the leading end, and a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). Flexible member 118 is at least in part curved when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member is curved when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5). At least one of flexible projections 116 is capable of flexing (Specification, page 6, line 27) toward shaft 112 when being inserted in the tissue (Fig. 7).

Independent claim 60.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 is made of a bioabsorbable material (Specification, page 6, lines 27-31), and comprises a shaft 112 (Specification, page 7, lines 6-8; Fig. 5) having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has a maximum cross-sectional dimension transverse to

the mid-longitudinal axis (Fig. 5), is at least in part conical at the leading end and has a flexible member 118 (Specification, page 7, line 6; Fig. 5) at trailing end 120. Flexible member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and a dimension larger than the maximum cross-sectional dimension of shaft 112. Flexible member 118 is adapted to deform so as to conform to the surface of the tissue in which the rivet is inserted. (Specification, page 6, lines 31-33). The top of flexible member 118 is at least in part concave when flexible member 118 is in contact with the tissue M (Fig. 2; the meniscus is concave (see Exhibit A), thus the top of the flexible member will be concave when in contact with the tissue of the meniscus). Shaft 112 has a plurality of flexible projections 116 (Specification, page 7, lines 2-5; Fig. 5) extending radially from shaft 112. Flexible projections 116 are separate and spaced apart from one another (Fig. 5).

Independent claim 100.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). Flexible member 118 is at least in part curved when the bottom of flexible member 118 contacts the tissue. (Fig. 2; the meniscus is curved (see Exhibit A), thus the flexible member will be curved when in contact with the tissue of the meniscus).

Independent claim 144.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a

mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top, the bottom adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a portion of the bottom of flexible member 118 forms an included angle relative to the mid-longitudinal axis of shaft 112 that is greater than 90 degrees. (Fig. 7; see also Exhibit D, angle A).

Independent claim 176.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a flexible member 118 proximate trailing end 120 of shaft 112. Flexible member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). Flexible member 118 has an outer perimeter between the top and the bottom (Fig. 5), at least a portion of the outer perimeter being flexible relative to shaft 112 when rivet 100 is inserted into the tissue. (Specification, page 6, lines 31-33; Figs. 6-7).

Independent claim 211.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5), a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8)

and a bottom (Fig. 5) opposite the top, and an outer perimeter, the bottom being adapted to contact tissue upon insertion of rivet 100 into the tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A), at least a second portion of the bottom adjacent to the outer perimeter is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Independent claim 242.

The present invention in another preferred embodiment is directed to a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5) for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together. Rivet 100 comprises a shaft 112 having a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a mid-longitudinal axis (Specification, page 7, line 7) therebetween. Shaft 112 has an exterior surface with at least one projection 116 adapted to resist expulsion of rivet 100 from within the tissue. (Specification, page 3, lines 23-25). Rivet 100 includes a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8) and a bottom (Fig. 5) opposite the top that is adapted to contact tissue. (Fig. 7). At least a portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7). Member 118 has a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape. (Figs. 6-7).

Independent claim 273.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, a mid-longitudinal axis (Specification, page 7, line 7) therebetween, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, the bottom being adapted to contact tissue (Fig. 7). At least a

portion of member 118 is moveable relative to shaft 112 between an undeployed position where the bottom surface is not in contact with the tissue (Fig. 6) and a deployed position where the bottom surface contacts the tissue (Fig. 7), the member having a first shape in the deployed position (Fig. 6) and a second shape in the undeployed position (Fig. 7), the first shape being different from the second shape (Figs. 6-7). The method also includes the steps of inserting rivet 100 into the tissue until the bottom contacts the tissue (Specification, page 7, lines 27-29; Figs. 6-7); and moving at least a portion of the member relative to the shaft to the deployed position (Specification, page 7, lines 29-31; Fig. 7).

Independent claim 283.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a flexible member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top. The method also comprises the steps of engaging a driving instrument 130 to rivet 100 (Specification, page 7, lines 21-23; Figs. 5-6); and inserting rivet 100 into the tissue until the bottom of flexible member 118 contacts the tissue (Specification, page 7, lines 27-29) and flexible member 118 deforms to conform to the curvature of the tissue adjacent 100 rivet (Specification, page 7, lines 29-31; Figs. 6-7).

Independent claim 293.

The present invention in another preferred embodiment is directed to a method for holding pieces of tissue M (Specification, page 6, lines 7-19; Fig. 4) together with a tissue rivet 100 (Specification, page 7, lines 1 and 2; Fig. 5). The method comprises the step of providing rivet 100 having a shaft 112 with a leading end (Fig. 5) for insertion first into the tissue, a trailing end 120 (Fig. 5) opposite the leading end, and a member 118 proximate trailing end 120 of shaft 112. Member 118 has a top (Fig. 8), a bottom (Fig. 5) opposite the top, and an outer perimeter (Fig. 5). The method also includes the step of inserting rivet 100 into the tissue until the bottom of member 118 contacts the

tissue (Fig. 7). At least a first portion of the bottom adjacent to the outer perimeter of member 118 is at an acute angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle A). At least a second portion of the bottom adjacent to the outer perimeter of member 118 is at an obtuse angle relative to the mid-longitudinal axis of shaft 112 (Fig. 7; see also Exhibit D, angle B).

Grounds of Rejection to be Reviewed on Appeal

I. The amendment filed January 7, 2004 (the "January 2004 Amendment") stands objected to under 35 U.S.C. § 132 for introducing new matter. In particular, the Examiner contends that the phrases listed below and recited in the claims are not supported by the original disclosure.

A. "[S]aid flexible member being at least in part curved" (corresponding to item (a) of the objection under 35 U.S.C. § 132 on page 2 of the Final Office Action dated March 19, 2004 (the "March 2004 Office Action").

B. "[S]aid flexible member is deformable to have an at least in part concave shape" (corresponding to item (b) of the March 2004 Office Action).

C. "[S]aid flexible member has a greater surface area to mass ratio than said shaft" (corresponding to item (c) of the March 2004 Office Action).

D. "[S]aid flexible member has a smaller mass than the mass of said shaft" (corresponding to item (d) of the March 2004 Office Action).

E. "[A]t least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" (corresponding to item (i) of the March 2004 Office Action).

F. "[A]t least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" (corresponding to item (k) of the March 2004 Office Action).

G. "[A]t least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" (corresponding to item (l) of the March 2004 Office Action).

II. The specification stands objected to under 35 U.S.C. § 112, first paragraph, as not providing support as originally filed for claims 29-300 (under Ground I, sub-grounds A to G, listed above).

III. Claims 29-300 stand rejected under 35 U.S.C. § 112, first paragraph, as not being adequately described by the specification (under Ground I, sub-grounds A to G, listed above).

IV. Claims 29-300 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

V. Claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

VI. Claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren.

VII. Claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); U.S. Patent No. 4,728,238 to Chisholm et al. ("Chisholm") or U.S. Patent No. 4,422,276 to Paravano ("Paravano").

VIII. Claims 87, 88, 131, and 132 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons").

Argument

The Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

I. Objection to the amendment filed January 7, 2004 under 35 U.S.C. § 132.

A. The phrase "said flexible member being at least in part curved" applicable to independent claims 29 and 100.

Appellant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry, 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis

added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground A as lacking support has been overcome.

For the foregoing reasons, the Examiner's contention in the November 2004 Advisory Action "that the specification states that the flexible member deforms to the surface of the meniscus at an 'angle of the meniscus' not to the curve of the meniscus" is unfounded. (See November 2004 Advisory Action, page 2).

B. The phrase "said flexible member is deformable to have an at least in part concave shape" applicable to claims 33, 105, 148, 183, 214, and 245.

The remarks under item I(A) of the argument above are incorporated by reference herein. Further, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member can have a curved top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground I, sub-ground B as lacking support has been overcome.

C. The phrase "said flexible member has a greater surface area to mass ratio than said shaft" applicable to claims 34, 65, 106, 149, 184, 215, and 246.

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example in Fig. 4. (A copy of Fig. 4 is attached hereto as Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co of America v. United*

States, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Examiner's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground C.

D. The phrase "said flexible member has a smaller mass than the mass of said shaft" applicable to claims 35, 66, 107, 150, 185, 216, and 247.

The remarks under item I(C) of the argument above are incorporated by reference herein. Further, the flexible member having a smaller mass than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B).

As the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground I, sub-ground D.

E. The phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees" applicable to claim 145.

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); a

copy of page 588 is attached hereto as Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, a copy of which is attached hereto as Exhibit D).

Appellant respectfully traverses the Examiner's contention that the claim "positively recites that the flexible member is designed with this angle of less than 90 degrees." (November 2004 Advisory Action, page 2). Claim 145 recites that "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis that is less than 90 degrees." (Emphasis added). Appellant respectfully submits that the claim is not limited to a "pre-formed" angle of less than 90 degrees as the Examiner contends, but includes the rivet being deformable to "form" the angle of less than 90 degrees upon insertion into the meniscus. This is clearly supported in Fig. 7. Moreover, the Examiner has agreed that the claimed angle exists "after it [the flexible member] has been deformed during use." (November 2004 Advisory Action, page 2). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground E.

F. The phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

Appellant respectfully traverses the Examiner's contention that the claimed angles "are not properties of the device as made." (November 2004 Advisory Action, page 2). The claimed angles must be a property of the rivet as made, otherwise the rivet would not be able to deform to the angle shown in Fig. 7. Accordingly, Appellant

submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground F.

G. The phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft" applicable to independent claims 211 and 293.

The remarks under item I(F) of the argument above are incorporated by reference herein. Further, the bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground I, sub-ground G.

Appellant submits that the Examiner's objection to the January 2004 Amendment under 35 U.S.C. § 132 has been overcome.

II. Objection to the specification under 35 U.S.C. § 112, first paragraph, as not supporting the invention as now claimed.

Appellant respectfully submits that the objection to the specification under 35 U.S.C. § 112, first paragraph as not supporting the invention as now claimed is overcome in view of Appellant's remarks addressing the objection to the Amendment filed January 7, 2004 under 35 U.S.C. § 132 above, those remarks being incorporated by reference herein. (See items I(A) to I(G) of the argument above).

III. Rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not adequately described as set forth in the objection to the specification under Ground I above.

Appellant respectfully submits that the rejection improperly rejects all claims even though many claims do not include the features which the Examiner contends is not supported. In particular, Appellant submits that the features which the Examiner identified as not being adequately supported concern only claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300. The Examiner has not

provided any rationale as to why claims 60-64, 67-99, 144, 146, 147, 151-182, 186-210, 242-244, and 248-292 are rejected under 35 U.S.C. § 112, first paragraph. Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 65, 66, 100-143, 145, 148-150, 183-185, 211-241, 245-247, and 293-300 is addressed below.

A. Claims 29-59 and 100-143 concerning the phrase "said flexible member being at least in part curved" as recited in independent claims 29 and 100.

Appellant discloses that the flexible member is flexible "so as to be able to conform to the angle of the meniscus M," and "deform so as to conform to the surface of the meniscus." (Specification, page 6, lines 31-33; and page 7, lines 30-31). It is well known to those skilled in the art of orthopedic surgery that the surface of the meniscus is curved. (See, e.g., Anatomy of the Human Body, Gray Henry. 20th ed., Fig. 349 (1918), a copy of which is attached hereto as Exhibit A). The surgeon installs the rivet of the present invention by inserting the shaft into the tissue of the torn meniscus. After the rivet is fully deployed, the shaft will have penetrated the portions of the meniscus tissue being repaired and the flexible member will be in contact with surface of meniscus. When the flexible member contacts the surface of the meniscus, due to the curvature of the meniscus, the forces between the underside of the flexible member and the tissue of the meniscus cause at least a portion of the perimeter of the flexible member to flex away from the shaft. As a result, at least a portion of the perimeter is elevated relative to the middle of the flexible member overlying the shaft, which is held in place by the shaft. This deformation of the flexible member forms a curve to conform to the curve of the top surface of the meniscus into which the flexible member is inserted. As a result of the deformation, the top surface of the flexible member can become curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member is "at least in part curved" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being at least in part curved when in contact with the tissue is inherently supported in the specification and drawings

of Appellant's disclosure as originally filed. According to the MPEP, "[b]y disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application *necessarily* discloses that function, theory or advantage, even though it says nothing explicit concerning it." (MPEP § 2163.07(a), page 2100-184, col. 1 (May 2004)) (emphasis added). Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground A as lacking support has been overcome.

B. Claims 33, 105, 148, 183, 214, and 245 concerning the phrase "said flexible member is deformable to have an at least in part concave shape."

The remarks under item III(A) of the argument are incorporated by reference herein. Further, as a result of the deformation of the flexible member against the surface of the meniscus, the top surface of the flexible member becomes curved to create a concavity in the top surface of the flexible member. Accordingly, Appellant submits that the disclosure readily allows one of ordinary skill in the art to perceive that the flexible member has a top surface with a shape that is "at least in part concave" when in contact with the tissue of the meniscus.

Appellant further submits that the flexible member being deformable to have an at least in part concave shape when in contact with the tissue is inherently supported in the specification and drawings of Appellant's disclosure as originally filed. Accordingly, Appellant submits that the Examiner's objection to the subject matter identified in Ground III, sub-ground B as lacking support has been overcome.

C. Claims 34, 65, 106, 149, 184, 215, and 246 concerning the phrase "said flexible member has a greater surface area to mass ratio than said shaft."

The flexible member having a greater surface area to mass ratio than that of the shaft is supported in the original disclosure at least, for example, in Fig. 4. (See Fig. 4, Exhibit B). The figures can provide support for the claimed invention to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. MPEP § 2163(II)(A)(3)(a) states that "[a]n Appellant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that Appellant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, [citation omitted], ("drawings alone may provide a 'written description' of an

invention as required by sec. 112"); *In re Wolfensperger*, [citation omitted], (the drawings of Appellant's specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, [citation omitted], ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner with the same limitations as the specification.") (MPEP § 2163(II)(A)(3)(a), page 2100-170, col. 2 to page 2100-171, col. 1 (May 2004)).

As shown in Fig. 4, the flexible member has a greater surface area to mass ratio than the shaft. To facilitate the Board's understanding of the difference in the surface area to mass ratios, Appellant measured the dimensions of the rivet in Fig. 4 and used these dimensions to calculate their respective ratios. (See Fig. 4, and calculations on page 2 of Exhibit B). In Fig. 4, the surface area to mass ratio of the flexible member is 0.54. The surface area to mass ratio of the shaft is 0.34. Appellant's calculations show, with mathematical certainty, that the flexible member has a greater surface area to mass ratio than the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground C.

D. Claims 35, 66, 107, 150, 185, 216, and 247 concerning the phrase "said flexible member has a smaller mass than the mass of said shaft."

The remarks under item III(C) of the argument are incorporated by reference herein. Further, as the flexible member and shaft are made of the same material, it is clear from Fig. 4 that the mass of the flexible member is less than the mass of the shaft. (See Fig. 4, Exhibit B). Accordingly, Appellant submits that the disclosure as originally filed supports the relationship set forth in Ground III, sub-ground D.

E. Claim 145 concerning the phrase "at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support a second portion of the bottom of the flexible member forming an included angle relative to the mid-longitudinal axis of the shaft that is less than 90 degrees. An "included angle" is defined as an angle "between or within" two sides. (Merriam Webster's Collegiate Dictionary, 10th ed., page 588, col. 1 (1999); Exhibit C). Appellant discloses in Fig. 7 an included angle between the bottom of the

flexible member and the mid-longitudinal axis of the shaft that is less than 90 degrees. (See angle A as labeled in Fig. 7, Exhibit D). Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground E.

F. Claims 211-241 and 293-300 concerning the phrase "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft" as recited in independent claims 211 and 293.

The bottom of the flexible member having a first portion adjacent the perimeter being at an acute angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an acute angle (angle A in Exhibit D) between a first part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground F.

G. Claims 211-241 and 293-300 concerning the phrase "at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis" as recited in independent claims 211 and 293.

The bottom of the flexible member having a second portion adjacent the perimeter being at an obtuse angle relative to the mid-longitudinal axis of the shaft is supported in the original disclosure at least, for example, in Fig. 7. (See Exhibit D). As shown in Fig. 7, there is an obtuse angle (angle B in Exhibit D) between a second part of the bottom of the flexible member adjacent the outer perimeter and the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the disclosure as originally filed supports the angular relationship set forth in Ground III, sub-ground G.

Appellant submits that the Examiner's rejection of claims 29-300 under 35 U.S.C. § 112, first paragraph for failing to provide support for the invention as now claimed has been overcome.

IV. Rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.

Appellant respectfully submits that this rejection is improper because the Examiner's rationale for supporting the rejection relates to issues of inadequate written support and not to indefiniteness, which is an issue under 35 U.S.C. 112, first paragraph, not second paragraph.

Moreover, Appellant respectfully submits that the Examiner has again improperly rejected all claims when the features identified by the Examiner as allegedly lacking support are not applicable to all claims. In particular, the features identified by the Examiner as allegedly lacking support concern only claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 as they existed before the entry of the September 2004 Amendment. The Examiner has not provided any rationale as to why claims 60-71, 74, 76-94, 96-99, 144, 146, 147, 149-155, 157, 159-172, 174-182, 184-190, 192, 194-207, 209, 210, 242-244, 246-252, 254, 256-269, and 271-292 are rejected under 35 U.S.C. § 112, second paragraph. Accordingly, Appellant submits that these claims are allowable despite the Examiner's blanket rejection of all claims. The Examiner's rejection as it concerns claims 29-59, 72, 73, 75, 95, 100-143, 145, 148, 156, 158, 173, 183, 191, 193, 208, 211-241, 245, 253, 255, 270, and 293-300 is addressed below.

A. Claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 concerning the phrase "along the mid-longitudinal axis."

In order to expedite prosecution, Appellant amended claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 in the September 2004 Amendment to change "along" to "around" as indicated by the Examiner as being supported in the disclosure as originally filed. (See March 2004 Office Action, page 3, last full paragraph). The amendment was entered by the Examiner. (November 2004 Advisory Action). The claims now recite that the projections are oriented in arrays "around the mid-longitudinal axis of said shaft." Accordingly, Appellant submits that the rejection of claims 40, 41, 72, 73, 114, 115, 156, 191, 222, and 253 has been overcome.

B. Claims 43, 75, 117, 158, 193, 224, and 255 concerning the phrase "at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft."

Appellant respectfully disagrees with the Examiner's contention that the original disclosure does not support at least two flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Appellant discloses at least two flexible projections *extending* from the shaft in the same plane in Fig. 1. A copy of Fig. 1 is attached hereto as Exhibit E with a transverse plane drawn thereon showing two of the flexible projections extending from the shaft along a plane "P."

Moreover, Appellant notes that the Examiner's position in the March 2004 Office Action is inconsistent with the Examiner's earlier position stated in the Office Action dated July 7, 2003. In that Office Action, the Examiner stated that "[i]t would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis." (Office Action dated July 7, 2003, page 4, paragraph 2). Appellant submits that the disclosure as originally filed supports at least two of the flexible projections extending from the shaft in the same plane transverse to the mid-longitudinal axis of the shaft. Accordingly, Appellant submits that the rejection of claims 43, 75, 117, 158, 193, 224, and 255 has been overcome.

C. Claims 56, 95, 139, 173, 208, 239, and 270 concerning the rivet being approximately 10 mm in length.

In order to expedite prosecution, Appellant amended claims 56, 95, 139, 173, 208, 239, and 270 in the September 2004 Amendment to change "10 mm" to "8 mm," which is supported in the specification on page 8, line 4. The amendment was entered by the Examiner. (November 2004 Advisory Action). Accordingly, Appellant submits that the rejection of claims 56, 95, 139, 173, 208, 239, and 270 has been overcome.

D. Claims 29-59 and 100-143 concerning the flexible member being at least in part curved (recited in independent claims 29 and 100); claims 33, 105, 148, 183, 214, and 245 concerning the flexible member being at least in part concave; and claims 145, 211-241, and 293-300 concerning the member being at an angle not perpendicular to the mid-longitudinal axis.

Appellant submits that the rejection of claims 29-59, 100-143, 145, 148, 183, 211-241, 245, and 293-300 are overcome based on Appellant's remarks addressing the

Examiner's rejection of these claims under 35 U.S.C. § 112, first paragraph above, these remarks being incorporated by reference herein. (See items III(A), III(B), III(E), III(F), and III(G) of the argument above).

Appellant submits that the rejection of claims 29-300 under 35 U.S.C. § 112, second paragraph, as being indefinite has been overcome.

V. The rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,261,914 to Warren ("Warren").

A. Arguments applicable to all claims under the current rejection: the Examiner's rationale for supporting the rejection in view of Warren is inconsistent with the teachings of Warren.

1. The structure of the head taught by Warren cannot be ignored.

The Examiner states that "[d]ue to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that [the] rivet of Warren would comprehend the claimed resilient characteristic at least to some extent." (March 2004 Office Action, paragraph bridging pages 4 and 5). By focusing only on the material of the Warren fastener, the Examiner is ignoring the structure of the fastener taught by Warren. Warren teaches that head 110 has a thickness greater than the wall thickness of the shank. (See Warren, col. 3, lines 38-40, 46, and 47; col. 4, lines 66-67). The thickness of the shank wall is obtained by subtracting the rib diameter, 0.157 inches, from the diameter of the internal bore, 0.048 inches, and then dividing the result by two to arrive at 0.0545 inches, which is less than the 0.069 inch thickness of the head. If the head of the Warren fastener were flexible enough to deform to conform to the surface of the tissue as recited, for example, in claims 29 and 60, then shank of the Warren fastener would have insufficient rigidity to withstand repeated blows to be driver into the bone. This result follows because the head has a thickness greater than the wall of the shank. (See, e.g., Warren, Fig. 1). Thus, if the head were modified to be sufficiently flexible as recited in claims 29 and 60, then the shank would be even more flexible because it is thinner than the head. This, of course, ignores any effect of fillet 161, which as

discussed above would operate to inhibit flexibility. Modifying the head of the Warren fastener as suggested by the Examiner would render the shank of the Warren fastener unsatisfactory for its purpose of being able to be driven into bone or bone-like structures. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-129, col. 2 (May 2004)).

2. The context in which the Warren fastener is used must be considered.

Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). The Examiner states that "[t]he only difference between the claims and Warren's device is that the claims recite that the flexible head member deforms when it is pounded into place. Inherently any head member made of a polymeric material when pounded into place on a surface that is curved or irregular will deform at least to a certain extent." (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). First, Appellant's claims do not recite that the flexible member is "pounded into place." Second, assuming *arguendo* that there were any deformation of the head of Warren during insertion, such deformation would be due to the repeated striking of the head to pound the fastener into the bone, not due to the resilient nature of the flexible member conforming to the surface of tissue.

The Examiner further states that "[b]ecause different portions of the head will come into contact with the bone at different times the head will deform as one portion of the head cannot move and other portions continue to move closer to the bone." (March 2004 Office Action, page 5, paragraph bridging pages 4 and 5). Appellant respectfully submits that the Examiner is ignoring the context in which Warren teaches using the fastener. Warren teaches driving the fastener through ligament 200 and into bone 300. (Warren, col. 5, lines 13-14; Figs. 7 and 8). As the fastener is pounded into the bone, the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16). The head taught by Warren is not designed to be used against bone, but rather "ligaments or ligament-like objects." (Warren, col. 7, lines 28-29). As the head of the Warren fastener is pounded in, it will contact the softer ligament. Thus, any deformation as between the head and the ligament will be confined to the ligament deforming, not the

head. To attempt to use the fastener of Warren to attach only bone segments together would change the principal operation of the Warren fastener. The Examiner's modification of the principal of operation of the Warren fastener is not permissible. (See MPEP § 2143.01, "The Proposed Modification Cannot Change the Principle of Operation of a Reference," page 2100-132, col. 1 (May 2004)).

3. The Examiner's redesign of the Warren fastener is without teaching or suggestion.

The Examiner states that "Warren teaches that the fastener can be thinner." (March 2004 Office Action, page 5, paragraph bridging pages 5 and 6). The Examiner then redesigns the Warren fastener to fit within the scope of Appellant's claimed invention. (See March 2004 Office Action, paragraph bridging pages 5 and 6). The Examiner states that a thinner fastener "would then result in a head member that would flex as it is forced into contact with the bone," and that finding the right dimensions "would result in a head that flexes during implantation." (March 2004 Office Action, paragraph bridging pages 5 and 6). Appellant respectfully submits that the Examiner's redesign of the Warren fastener is improper. First, the Examiner has not provided any motivation as to why one would modify the Warren fastener to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6) (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Second, modifying the Warren fastener as suggested by the Examiner render it unsuitable for its intended purpose of being able to be pounded into bone as taught by Warren. (See MPEP § 2143.01, "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For its Intended Purpose," page 2100-131, col. 2 (May 2004)). Accordingly, the Examiner's proposed redesign of the Warren fastener cannot be applied in the rejection.

4. The Examiner is using impermissible hindsight.

Appellant also submits that the Examiner is using impermissible hindsight in order to fashion a motivation to support the rejection. The Examiner states that "it would have been obvious to modify the rivet of Warren" to have "a head that flexes." (March 2004 Office Action, page 6, paragraph bridging pages 5 and 6). Such a motivation is not suggested in the art cited by the Examiner. In the specification,

Appellant teaches a flexible member that is "sufficiently flexible so as to be able to conform to the angle of the meniscus." (Specification, page 6, lines 31-33). Appellant submits that prior to Appellant's teachings, there was no motivation to have a head that flexes.

It is respectfully submitted that the Examiner is using impermissible hindsight by gleaning the motivation used to reject the present claims over Warren from Appellant's own teachings in the specification. (See MPEP § 2141.01(III), page 2100-121, col. 2 (May 2004) ("[i]t is difficult but necessary that the decision-maker forget what he or she has been taught...about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." (citation omitted)). Appellant respectfully submits that the rejection was not framed with the mind of one skilled in the art presented only with the references and then-commonly accepted wisdom in the art, but with the guidance of Appellant's teachings. It is therefore submitted that a *prima facie* case of obviousness has not been established.

B. Arguments applicable to separately grouped claims.

1. Claims 29-31, 33-37, and 44-52.

Warren teaches away from the claimed invention. Warren discloses a surgical fastener for attaching soft tissues to bone or bone-like structures. (Warren, col. 7, lines 22-31). In order to insert the fastener into the bone, Warren teaches that head 110 is repeatedly struck in order to drive fastener 100 through the tissue and into the bone. (Warren, col. 5, lines 8-16; and Figs. 6-8). Accordingly, the structure of head 110 must be able to withstand repeated blows to drive the fastener into bone.

Warren discloses two ways that the head is made sufficiently rigid to withstand pounding. First, head 110 is made thick. Warren teaches that the thickness of head 110 is 0.069 inches, which is more thick than any part of the shank wall 115 perpendicular to the longitudinal axis of the fastener. (Warren, col. 3, lines 38-40; Fig. 1). Secondly, Warren teaches the use of a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110. (Warren, col. 3, lines 40-42). As is

known in the art, fillets are used to reinforce a corner where two surfaces meet. (See, e.g., Merriam Webster's Collegiate Dictionary, 10th ed., page 435, col. 1 (1999); a copy of page 435 is attached hereto as Exhibit F). Accordingly, the head of the Warren fastener is rigid in order to withstand repeated pounding so that the fastener can be driven into bone.

Independent claim 29 recites a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 29.

Not only does Warren not teach or suggest a rivet as recited in claim 29, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 29 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 29.

2. Claim 32.

Appellant further submits that the cited art, whether alone or in proper combination, fails to teach or suggest the subject matter of claim 32. Claim 32 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contends that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

Pursuant to MPEP 2144.03(c), Appellant challenged the Examiner's assertion that the skin rubbing over the head of a tissue fastener is a well-recognized problem in the art that is solved by making the heads flush. (See MPEP 2144.03(c), "[i]f Appellant challenges a factual assertion as not properly Officially Noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence," page 2100-138, col. 1 (May 2004)). First, the skin of a patient makes no contact with a trailing end of a rivet that is inserted into the meniscus of the knee. The

flexible member of the rivet taught by Appellant is configured to minimize interference with normal knee-joint motion, not skin abrasion. Second, none of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, a flexible member having a beveled outer edge. (See, e.g., Bays, Fig. 3; Warren, Fig. 8; and Duncan, Fig. 9). Also, according to the MPEP, "[i]f the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2)." (MPEP 2144.03(c), page 2100-138, col. 1 (May 2004)).

In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 32 should be withdrawn.

3. Claims 60-63, 65-69, 76-86, and 95-99.

Independent claim 60 recites the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and the top of the flexible member being "at least in part concave when said flexible member is in contact with the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part concave as recited in claim 60.

Not only does Warren not teach or suggest a rivet as recited in claim 60, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 60 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 60.

4. Claim 64.

Claim 64 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 64 should be withdrawn.

5. Claims 100-103, 105-111, 114, 115, 118-130, and 139-143.

Independent claim 100 recites the flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue." As shown in Fig. 8 of Warren, the reinforced head of fastener 100 remains straight when in contact with tissue after insertion. There is no teaching or suggestion in Warren of the flexible member being at least in part curved when in contact with tissue as recited in claim 100.

Not only does Warren not teach or suggest a rivet as recited in claim 100, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 100 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 100.

6. Claim 104.

Claim 104 recites the flexible member having an outer edge that is beveled. In the March 2004 Office Action, the Examiner contended that "making the head of the fastener less obtrusive so that it is flush with the bone surface so that the skin does not rub against the head is a well-recognized problem in the art." (March 2004 Office Action, page 6, paragraph 1).

In accordance with MPEP 2144.03(c), Appellant challenged the Examiner's assertion. (See remarks concerning claim 32 above (item V(B)(2) of the argument), which are incorporated by reference herein). In the November 2004 Advisory Action, the Examiner failed to provide the evidence requested by Appellant in accordance with MPEP § 2144.03(c). Accordingly, Appellant submits that the rejection of claim 104 should be withdrawn.

7. Claims 144-153, 156, 159-167, and 173-175.

Independent claim 144 recites at least a portion of the bottom of the flexible member "forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees." Warren teaches a fastener with a head having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claim 144.

Not only does Warren not teach or suggest a rivet as recited in claim 144, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 144 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 144.

8. Claims 176-188, 191, 194-202, and 208-210.

Independent claim 176 recites the flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to said shaft when said rivet is inserted into the tissue." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or suggest a tissue rivet as recited in independent claim 176.

Not only does Warren not teach or suggest a rivet as recited in claim 176, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 176 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 176.

9. Claim 192.

Dependent claim 192 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." Warren does not teach or suggest such a configuration. Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 192. Therefore, it is

submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 192 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

10. Claims 211-219, 222, 225-233, and 239-241.

Independent claim 211 recites a member having a bottom, "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft." Warren teaches a fastener with a head having a bottom that is perpendicular to the mid-longitudinal axis of the shank. (See Warren, Fig. 8). Warren does not teach or suggest a tissue rivet having the angular relationship as recited in independent claim 211.

Not only does Warren not teach or suggest a rivet as recited in claim 211, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 211 by using a head design that must be perpendicular to the longitudinal axis of the shank to facilitate the insertion of the fastener by repeated pounding. (See Warren, Figs. 6-8). If the head of the Warren fastener were angled as recited in claim 211, repeatedly striking the head as taught by Warren to insert the fastener would be made more difficult because a portion of the vertical insertion force would be translated laterally and the fastener would be more difficult to insert. Accordingly, Appellant submits that Warren teaches away from Appellant's claimed invention. (See MPEP §2141.02, "Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims," page 2100-127, col. 1 (May 2004)).

11. Claims 242-250, 253, 256-264, and 270-272.

Independent claim 242 recites a member, "at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape." The head taught by Warren is not configured for moving or flexing, at least due to the greater thickness of the head relative to the shank, and fillet 161 as discussed above. (See, e.g., Warren, Fig. 1). Warren does not teach or

suggest a tissue rivet as recited in independent claim 242.

Not only does Warren not teach or suggest a rivet as recited in claim 242, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 242 using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not moveable as recited in independent claim 242.

12. Claims 273-276, 278, 279, and 282.

Independent claim 273 recites a method for holding pieces of tissue together, including the steps of providing the rivet with a member having a bottom, "at least a portion of the member being moveable relative to the shaft between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape," and "moving at least a portion of the member relative to the shaft to the deployed position." Warren teaches driving the fastener into the bone and so that the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 273.

Not only does Warren not teach or suggest a method as recited in claim 273, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 273 using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not moveable as recited in independent claim 273.

13. Claims 283-285, 289, and 292.

Independent claim 283 recites a method including the step of inserting a rivet into the tissue "until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet." Warren teaches driving the fastener into the bone and so that the head "captivates the

ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 283.

Not only does Warren not teach or suggest a method as recited in claim 283, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 283 by using a head design that must have a sufficient rigidity to withstand repeated blows to drive the fastener into bone. Such a fastener teaches away from Appellant's claimed invention because its head is not flexible as recited in independent claim 283.

14. Claims 293, 294, 296, 297, and 300.

Independent claim 293 recites a method including the step of inserting a rivet into the tissue "until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft." Warren teaches driving the fastener into the bone and so that the head "captivates the ligament against the bone." (Warren, col. 5, lines 15-16; Fig. 8). As shown in Fig. 8 of Warren, when the ligament is "captivated," the bottom of the head remains perpendicular to the mid-longitudinal axis of the shank. Accordingly, Warren does not disclose a method as recited in claim 293.

Not only does Warren not teach or suggest a method as recited in claim 293, Warren teaches away from the subject matter of this claim. Warren teaches away from claim 293 by using a head design that must be perpendicular to the longitudinal axis of the shank to facilitate the insertion of the fastener by repeated pounding. (See Warren, Figs. 6-8). If the head of the Warren fastener were angled as recited in claim 293, repeatedly striking the head as taught by Warren to insert the fastener would be made more difficult because a portion of the vertical insertion force would be translated laterally and the fastener would be more difficult to insert. Accordingly, Appellant submits that Warren teaches away from Appellant's claimed invention. (See MPEP § 2141.02, "Prior Art Must Be Considered In Its Entirety, Including Disclosures That

Teach Away From The Claims," page 2100-127, col. 1 (May 2004)).

Appellant submits that independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293 are patentable over Warren and that dependent claims 30-37, 44-52, 61-69, 76-86, 95-99, 101-111, 114, 115, 118-130, 139-143, 145-153, 156, 159-167, 173-175, 177-188, 191, 192, 194-202, 208-210, 212-219, 222, 225-233, 239-241, 243-250, 253, 256-264, 270-272, 274-276, 278, 279, 282, 284, 285, 289, 292, 294, 296, 297, and 300 are patentable over Warren at least because they depend from an allowable independent claim, or claims dependent therefrom.

Appellant submits that the rejection of claims 29-37, 44-52, 60-69, 76-86, 95-111, 114, 115, 118-130, 139-153, 156, 159-167, 173-188, 191, 192, 194-202, 208-219, 222, 225-233, 239-250, 253, 256-264, 270-276, 278, 279, 282-285, 289, 292-294, 296, 297, and 300 under 35 U.S.C. § 103 as being unpatentable over Warren has been overcome.

VI. The rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,976,715 to Bays et al. ("Bays") in view of Warren.

A. Arguments applicable to all claims under the current rejection.

1. The motivation used by the Examiner to support the combination of references is unsupportable.

Bays teaches a tack member 10 for repairing damaged tissue, a hollow applicator 20, and a needle 30 slidablely receivable in applicator 20 and tack member 10. (See Bays, col. 4, line 67 through col. 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (see Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, col. 5, lines 5-18).

The Examiner contends that "it would have been obvious to modify the rivet of Bays as taught by Warren to find the desired dimensions of a specific intended use that would be thin enough resulting in a head that flexes during implantation." (March 2004 Office Action, page 7, paragraph 1). Appellant respectfully submits that this motivation is unsupportable because it does not state why one of ordinary skill in the art would want to modify the head of Bays to flex. (See MPEP § 2143.01, "the Prior Art Must

Suggest the Desirability of the Claimed Invention," page 2100-129, col. 2 (May 2004)). Accordingly, Appellant respectfully submits that the rejection is unsustainable and must be withdrawn.

2. The combination of Bays and Warren teach away from Appellant's claimed invention.

Even assuming *arguendo*, that there was proper motivation to combine the repair tack of Bays with the fastener of Warren, the combination teaches away from Appellant's claimed invention. The J-configuration of the Bays applicator serves to restrain the head portion "against twisting or rotation about any axis extending vertically." (Bays, col. 5, lines 16 and 17). In order to serve its intended purpose, the head portion adapted to be used with the applicator of Bays must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. Appellant submits that if head 110 of the Warren fastener has the sufficient rigidity for use with the J-configuration of the applicator of Bays, then the proposed combination would not render Appellant's claimed invention obvious since a fastener head that is rigid enough to withstand axial movement and twisting or rotation about any vertical axis cannot be fairly said to be sufficiently flexible within the scope of Appellant's claimed invention.

B. Arguments applicable to separately grouped claims.

1. Claims 29-31, 33-37, 40, 41, and 44-59.

Even if the combination of Bays and Warren could be properly maintained, Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant. Both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member at the trailing end, the flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and being "at least in part curved when said flexible member is in contact with the tissue" as recited in independent claim 29.

2. Claim 32.

Dependent claim 32 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 32. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 32 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

3. Claims 60-63, 65-69, 72, 73, 76-86, and 89-99.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 60. As stated above in item V(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member being adapted to "deform so as to conform to the surface of the tissue in which said rivet is inserted," and the top of the flexible member being "at least in part concave when said flexible member is in contact with the tissue" as recited in independent claim 60.

4. Claim 64.

Dependent claim 64 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 64. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 64 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

5. Claims 100-103, 105-111, 114, 115, 118-130, and 133-143.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 100. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective

insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member being "at least in part curved when said bottom of said flexible member contacts the tissue" as recited in independent claim 100.

6. Claim 104.

Dependent claim 104 recites the flexible member having an outer edge that is beveled. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest such a configuration. (See, e.g., Bays, Fig. 3; and Warren, Fig. 8). Moreover, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 104. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 104 under 35 U.S.C. § 103(a) is improper and must be withdrawn.

7. Claims 144-153, 156, and 159-175.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 144. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member where at least a portion of the bottom of the flexible member forms "an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees" as recited in independent claim 144.

8. Claims 176-188, 191, and 194-210.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 176. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a flexible member having an outer perimeter, "at least a portion of said outer perimeter being flexible relative to

said shaft when said rivet is inserted into the tissue" as recited in independent claim 176.

9. Claims 211-219, 222, and 225-241.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 211. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a member having a bottom, "at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft" as recited in independent claim 211.

10. Claims 242-250, 253, and 256-272.

Appellant submits that the combination does not teach or suggest a tissue rivet as claimed by Appellant in independent claim 242. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a tissue rivet having a member, "at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape" as recited in independent claim 242.

11. Claims 273-276, 278-280, and 282.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 273. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper

combination, teach or suggest a method including the steps of providing the rivet with a member having a bottom, "at least a portion of the member being moveable relative to the shaft between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape," and "moving at least a portion of the member relative to the shaft to the deployed position" as recited in independent claim 273.

12. Claim 277.

Dependent claim 277 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claim 277 is allowable over the cited art.

13. Claim 281.

Dependent claim 281 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 281 is allowable over the cited art.

14. Claims 283-285, 289, 290, and 292.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 283. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper combination, teach or suggest a method including the step of inserting a rivet into the

tissue "until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet." Warren teaches driving the fastener into the bone and so that the head 'captivates the ligament against the bone" as recited in independent claim 283.

16. Claims 286 and 287.

Dependent claim 286 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claims 286 and 287 are allowable over the cited art.

16. Claim 288.

Dependent claim 288 recites the step of "snap-fitting the rivet onto a portion of the driving instrument." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 288 is allowable over the cited art.

17. Claim 291.

Dependent claim 291 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 291 is allowable over the cited art.

18. Claims 293, 294, 296-298, and 300.

Appellant submits that the combination does not teach or suggest a method as claimed by Appellant in independent claim 293. As stated above in item VI(B)(1) of the argument, both the repair tack of Bays and the fastener of Warren must have a head configuration that is rigid enough to withstand being inserted by the respective insertion tool taught by Bays and Warren. Neither Bays nor Warren, whether alone or in proper

combination, teach or suggest a method including the step of inserting a rivet into the tissue "until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft" as recited in independent claim 293.

19. Claim 295.

Dependent claim 295 recites the method step of inserting the shaft of the driving instrument into the passageway of the rivet until the face of the driving instrument contacts the top of the member. None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. The fastener of Warren is pounded into position. (Warren, col. 5, lines 8-16). The repair tack assembly of Bays is assembled by first "placing the cross bar portion 15 into slot 23 at the forward end of applicator 20," and then needle 30 is "slidably passed through the hollow applicator and bore 13 in tack member 10." (Bays, col. 6, lines 25-29). Accordingly, Appellant submits that claim 295 is allowable over the cited art.

20. Claim 299.

Dependent claim 299 recites the method step of "inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee." None of the art cited by the Examiner, whether alone or in proper combination, teach or suggest such a step. Accordingly, Appellant submits that claim 299 is allowable over the cited art.

Appellant notes that the remarks above pertaining to claims 277, 281, 286-288, 291, 295, and 295 were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant's position. Accordingly, Appellant's position on these claims stands unchallenged.

Appellant submits that independent claims 29, 60, 100, 144, 176, 211, 242, 273, 283, and 293 are patentable over Warren and Bays and that dependent claims 30-37, 40, 41, 44-59, 61-69, 72, 73, 76-86, 89-99, 101-111, 114, 115, 118-130, 133-143, 145-153, 156, 159-175, 177-188, 191, 194-210, 212-219, 222, 225-241, 243-250, 253, 256-272, 274-282, 284-292, and 294-300 are patentable over Warren at least because they

depend from an allowable independent claim, or claims dependent therefrom.

Appellant submits that the rejection of claims 29-37, 40, 41, 44-69, 72, 73, 76-86, 89-111, 114, 115, 118-130, 133-153, 156, 159-188, 191, 194-219, 222, 225-250, 253, and 256-300 under 35 U.S.C. § 103 as being unpatentable over Bays in view of Warren has been overcome.

VII. The rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan"); U.S. Patent No. 4,728,238 to Chisholm et al. ("Chisholm") or U.S. Patent No. 4,422,276 to Paravano ("Paravano").

A. Arguments applicable to all claims under the current rejection.

Appellant submits that Chisholm and Paravano are non-analogous art. The claims of the present invention are directed to a surgical tissue rivet and methods of surgery. Chisholm is directed to a plastic drive fastener for use in the automotive industry. (Chisholm, col. 2, lines 22-26). In particular, Chisholm states that "[t]he importance of the present invention relates to a plastic drive fastener which can be readily installed into an apertured panel or a bore within a thick panel in which the removal force is far in excess of the force of installation." (Chisholm, col. 2, lines 22-31). Paravano relates to "[a] door trim fastener assembly [that] includes a headed fastener overlying the backing layer of a trim panel and having a shank which extends through a slot in the trim panel." (Paravano, Abstract). Appellant states in the background of the specification that rivet-like tabs used in the automotive industry are "relatively large and have no application in a surgical procedure." (Specification, page 3, lines 18-20).

Appellant submits that the surgical field and the automotive field are non-analogous fields of endeavor and therefore cannot be combined to arrive at Appellant's claimed invention. (See MPEP § 2141.01(a), "Analogy in the mechanical arts," page 2100-123, cols. 1 and 2 (May 2004), which discusses *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992)("The court held the reference was not within the field of Appellant's endeavor, and was not reasonably pertinent to the particular problem with which the inventor was concerned because it had not been shown that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or

motivated to look to fasteners for garments."). Accordingly, Appellant submits that the rejection is unsustainable and must be withdrawn. Appellant notes that Chisholm was also cited in the Office Action dated July 11, 1994, but was successfully overcome after Appellant's reply dated March 17, 1995 in which Chisholm was asserted as being non-analogous art.

Appellant submits that even if Chisholm and Paravano are not included in the proposed combination of references to reject the claims under 35 U.S.C. 103(a), the rejections over claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 are rendered moot at least because they depend from an allowable independent claim, or claims dependent therefrom.

Appellant notes that the above remarks were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant's position. Accordingly, Appellant's position stands unchallenged.

B. Arguments applicable to separately grouped claims.

1. Claim 42.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 29 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(1) of the argument above). Further, dependent claim 42 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 42 is allowable over the analogous cited art.

2. Claim 74.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 60 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(2) of the argument above). Further, dependent claim 74 recites a

plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 74 is allowable over the analogous cited art.

3. Claim 116.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 100 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Further, dependent claim 116 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 116 is allowable over the analogous cited art.

4. Claim 157.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 144 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(4) of the argument above). Further, dependent claim 157 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary,

defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 157 is allowable over the analogous cited art.

5. Claim 192.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 176 in view of Bays and Warren is incorporated by refererice herein. (See items VI(A) and VI(B)(5) of the argument above). Further, dependent claim 192 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 192 is allowable over the analogous cited art.

6. Claim 223.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 211 in view of Bays and Warren is incorporated by refererice herein. (See items VI(A) and VI(B)(6) of the argument above). Further, dependent claim 223 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 223 is allowable over the analogous cited art.

7. Claim 254.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 242 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(7) of the argument above). Further, dependent claim 254 recites a plurality of projections "positioned in a radially staggered configuration along said shaft." None of the analogous art cited by the Examiner teach or suggest, whether alone or in proper combination, such a configuration.

Duncan teaches barbs being "equally spaced about the periphery of each leg." (Duncan, col. 11, lines 26-30 and Fig. 9). Merriam-Webster's Collegiate Dictionary, defines the term "stagger" as "marked by an alternating or overlapping pattern." (Merriam-Webster's Collegiate Dictionary, 10th Ed., page 1144, col. 1 (1999)). The equally spaced barbs in Duncan are not in an alternating or overlapping pattern. Accordingly, Appellant submits that claim 254 is allowable over the analogous cited art.

Appellant submits that the rejection of claims 38-43, 46-48, 70-75, 78-80, 112-117, 120-122, 154-161, 189-196, 220-227, 251-258 under 35 U.S.C. § 103(a) as being unpatentable over Bays and Warren, and further in view of Duncan, Chisholm, or U.S. Paravano has been overcome.

VIII. The rejection of claims 87, 88, 131, and 132 under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and Duncan, and further in view of U.S. Patent No. 4,338,835 to Simons ("Simmons").

A. Arguments applicable to all claims under the current rejection: the alleged equivalent must be an art recognized equivalent.

Bays teaches a hollow applicator 20, a needle 30 slidably receivable in applicator 20, and tack member 10. (Bays, col. 4, line 67 through col. 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (Bays, Fig. 1) which serves to restrain a grip portion 15 of the tack member. (Bays, col. 5, lines 5-18). Simmons teaches a driver 10 having a driver head 16 with four curved convex surfaces 22. (Simmons, col. 2, lines 49-57; Figs. 1 and 4). Simmons does not teach or suggest that driver head 16 is equivalent to the needle and J-shaped applicator combination of Bays. The Examiner states that "it would have been obvious to one of ordinary skill in

the art to further modify the prior art to use a spherical recess and cooperating driver as taught by Simmons as an obvious equivalent way of mating the driver to the fastener to force the fastener into place." (March 2004 Office Action, page 8, paragraph 2). According to the MPEP, "[i]n order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on Appellant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." (MPEP § 2144.06, page 2100-144, cols. 1 and 2 (May 2004), citing *In re Ruff*, 256 F.2d 590 (CCPA 1958)). Since Simmons fails to teach that his driver head is equivalent to the applicator configuration taught by Bays, the driver taught by Simmons cannot be cited as an obvious equivalent.

Appellant notes that the above remarks were presented in the September 2004 Amendment. The November 2004 Advisory Action did not present any arguments refuting Appellant's position. Accordingly, Appellant's position stands unchallenged.

B. Arguments applicable to separately grouped claims.

1. Claim 87.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 60 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument, as recited in claim 87. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

2. Claim 88.

Appellant's remarks in item VIII(B)(1) of the argument above are incorporated by reference herein. Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing

end that includes a depression that is at least in part spherical as recited in claim 88. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

3. Claim 131.

Appellant's remarks concerning the 35 U.S.C. § 103(a) rejection of independent claim 100 in view of Bays and Warren is incorporated by reference herein. (See items VI(A) and VI(B)(3) of the argument above). Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is configured to cooperatively engage a driver instrument, as recited in claim 131. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

4. Claim 132.

Appellant's remarks in item VIII(B)(3) of the argument above are incorporated by reference herein. Even if, assuming *arguendo*, the driver head of Simmons were an applicable mechanical equivalent, none of the art cited by the Examiner, whether alone or in proper combination, teach or suggest a tissue rivet having a shaft with a trailing end that includes a depression that is at least in part spherical as recited in claim 132. Simmons teaches a flat-headed machine screw 32 with four concave curved surfaces 38. (Simmons, col. 3, lines 12-16; Fig. 3). The machine screw taught by Simmons is not suitable for use as a tissue rivet in a surgical environment. Accordingly, Appellant submits that the rejection in view of Simmons is unsubstantiated and must be withdrawn.

Appellant submits that the rejection of claims 87, 88, 131 and 132 under 35 U.S.C. § 103(a) as being unpatentable over Bays, Warren, Chisholm, Paravano, and

Duncan, and further in view of Simons has been overcome.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: April 21, 2005

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CLAIMS APPENDIX

29. A tissue rivet for holding pieces of tissue together and to prevent movement of said rivet in the tissue, said rivet being made of a bioabsorbable material, said rivet comprising a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having a maximum cross-sectional dimension transverse to the mid-longitudinal axis, a truncated conical penetration head at said leading end, and a flexible member at said trailing end, said flexible member having a top, a bottom opposite said top, and a dimension larger than the maximum cross-sectional dimension of said shaft, said flexible member adapted to deform so as to conform to the surface of the tissue in which said rivet is inserted, said flexible member being at least in part curved when said flexible member is in contact with the tissue, said shaft having a plurality of flexible projections extending radially from said shaft, said flexible projections being separate and spaced apart from one another, at least one of said flexible projections capable of flexing toward said shaft when being inserted in the tissue.

30. The rivet of claim 29, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

31. The rivet of claim 29, wherein said flexible member is at least in part circular.

32. The rivet of claim 29, wherein said flexible member has an outer edge that is beveled.

33. The rivet of claim 29, wherein said top of said flexible member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said flexible member is in contact with the tissue.

34. The rivet of claim 29, wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

35. The rivet of claim 29, wherein said flexible member has a smaller mass than the mass of said shaft, whereby said flexible member is absorbed prior to said shaft so that said flexible member does not separate from said shaft.

36. The rivet of claim 29, including at least five of said flexible projections.
37. The rivet of claim 29, wherein said flexible projections are spaced apart from one another along the mid-longitudinal axis of said shaft.
38. The rivet of claim 29, wherein said flexible projections are spaced apart from one another about the mid-longitudinal axis shaft.
39. The rivet of claim 29, wherein said flexible projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.
40. The rivet of claim 29, wherein said flexible projections are oriented in at least two arrays around the mid-longitudinal axis of said shaft.
41. The rivet of claim 29, wherein said flexible projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.
42. The rivet of claim 29, wherein said flexible projections are positioned in a radially staggered configuration along said shaft.
43. The rivet of claim 29, wherein at least two of said flexible projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.
44. The rivet of claim 29, wherein said shaft has an exterior surface, said flexible projections extending from said exterior surface along approximately one half the length of said shaft.
45. The rivet of claim 29, wherein said shaft has an exterior surface, said flexible projections extending from said exterior surface along a portion of said shaft that is closer to said leading end of said shaft than said trailing end of said shaft.
46. The rivet of claim 29, wherein each of said flexible projections is a fin.
47. The rivet of claim 46, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.
48. The rivet of claim 47, wherein said distal edge of said fin is curved.
49. The rivet of claim 29, wherein said rivet comprises at least in part of a plastic material.
50. The rivet of claim 29, wherein said rivet comprises at least in part polyglycolic acid.

51. The rivet of claim 29, wherein said rivet comprises at least in part of a carbon composite.

52. The rivet of claim 29, wherein said rivet comprises at least in part of a pliable material.

53. The rivet of claim 29, wherein said shaft is hollow and further in combination with a driving instrument, said driving instrument comprising a rod having an outer diameter smaller than the inside diameter of said hollow shaft of said rivet and an upper handle portion having a diameter larger than the inside diameter of said hollow shaft of said rivet, said rod having a tapered tip, said tip forming the same angle as the angle of said conical penetration head of said rivet, whereby when said rod is fitted within said hollow shaft of the rivet, the surface of said tip of said driving instrument forms a smooth transition with said conical penetration head of said rivet.

54. The combination of claim 53, wherein the length of said rod from said handle to said tapered tip is longer than the length of said rivet.

55. The combination of claim 53, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.

56. The rivet of claim 29, wherein said rivet has a length of approximately 8 mm.

57. The rivet of claim 29, wherein said shaft of said rivet has a diameter of approximately 2 mm.

58. The rivet of claim 29, wherein said flexible member has a diameter of approximately 2.5 mm.

59. The rivet of claim 30, wherein said passageway has a diameter of approximately 1.25 mm.

60. A tissue rivet for holding pieces of tissue together, said rivet being made of a bioabsorbable material, said rivet comprising a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having a maximum cross-sectional dimension transverse to the mid-longitudinal axis, said shaft being at least in part conical at said leading end and having a flexible member at said trailing end, said flexible member having a top,

a bottom opposite said top, and a dimension larger than the maximum cross-sectional dimension of said shaft, said flexible member adapted to deform so as to conform to the surface of the tissue in which said rivet is inserted, said top of said flexible member being at least in part concave when said flexible member is in contact with the tissue, said shaft having a plurality of flexible projections extending radially from said shaft, said projections being spaced apart and separate from one another.

61. The rivet of claim 60, wherein said shaft is at least in part hollow.

62. The rivet of claim 60, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

63. The rivet of claim 60, wherein said flexible member is at least in part circular.

64. The rivet of claim 60, wherein said flexible member has an outer edge that is beveled.

65. The rivet of claim 60, wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

66. The rivet of claim 60, wherein said flexible member has a smaller mass than the mass of said shaft, whereby said flexible member is absorbed prior to said shaft so that said flexible member does not separate from said shaft.

67. The rivet of claim 60, wherein said leading end has a truncated leading portion.

68. The rivet of claim 60, including at least five of said flexible projections.

69. The rivet of claim 60, wherein said flexible projections are spaced apart from one another along the mid-longitudinal axis of said shaft.

70. The rivet of claim 60, wherein said flexible projections are spaced apart from one another about the mid-longitudinal axis shaft.

71. The rivet of claim 60, wherein said flexible projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.

72. The rivet of claim 60, wherein said flexible projections are oriented in at least two arrays around the mid-longitudinal axis of said shaft.

73. The rivet of claim 60, wherein said flexible projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.
74. The rivet of claim 60, wherein said flexible projections are positioned in a radially staggered configuration along said shaft.
75. The rivet of claim 60, wherein at least two of said flexible projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.
76. The rivet of claim 60, wherein said shaft has an exterior surface, said flexible projections extending from said exterior surface along approximately one half the length of said shaft.
77. The rivet of claim 60, wherein said shaft has an exterior surface, said flexible projections extending from said exterior surface along a portion of said shaft that is closer to said leading end of said shaft than said trailing end of said shaft.
78. The rivet of claim 60, wherein each of said flexible projections is a fin.
79. The rivet of claim 78, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.
80. The rivet of claim 79, wherein said distal edge of said fin is curved.
81. The rivet of claim 60, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.
82. The rivet of claim 60, wherein said rivet comprises at least in part of a plastic material.
83. The rivet of claim 60, wherein said rivet comprises at least in part polyglycolic acid.
84. The rivet of claim 60, wherein said rivet comprises at least in part of a carbon composite.
85. The rivet of claim 60, wherein said rivet comprises at least in part of a pliable material.
86. The rivet of claim 60, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.
87. The rivet of claim 60, wherein said trailing end of said shaft includes a depression configured to cooperatively engage a driver instrument.
88. The rivet of claim 87, wherein said depression is at least in part spherical.

89. The rivet of claim 60, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.

90. The combination of claim 89, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said passageway of said rivet.

91. The combination of claim 89, wherein said shaft of said driver has a length that is longer than the length of said rivet.

92. The combination of claim 89, wherein said shaft of said driver has a distal end with a sharp tip.

93. The combination of claim 92, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.

94. The combination of claim 89, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.

95. The rivet of claim 60, wherein said rivet has a length of approximately 8 mm.

96. The rivet of claim 60, wherein said shaft of said rivet has a diameter of approximately 2 mm.

97. The rivet of claim 60, wherein said flexible member has a diameter of approximately 2.5 mm.

98. The rivet of claim 62, wherein said passageway has a diameter of approximately 1.25 mm.

99. The rivet of claim 87, wherein said depression has a diameter of approximately 2 mm.

100. A tissue rivet for holding pieces of tissue together, said rivet comprising:

a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having an exterior surface with at least one projection adapted to resist expulsion of said rivet from within the tissue; and

a flexible member proximate said trailing end of said shaft, said flexible member having a top and a bottom opposite said top, said bottom adapted to contact tissue upon insertion of said rivet into the tissue, said flexible member being at least in part curved when said bottom of said flexible member contacts the tissue.

101. The rivet of claim 100, wherein said shaft is at least in part hollow.

102. The rivet of claim 100, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

103. The rivet of claim 100, wherein said flexible member is at least in part circular.

104. The rivet of claim 100, wherein said flexible member has an outer edge that is beveled.

105. The rivet of claim 100, wherein said top of said flexible member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said flexible member is in contact with the tissue.

106. The rivet of claim 100, wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

107. The rivet of claim 100, wherein said flexible member has a smaller mass than the mass of said shaft, whereby said flexible member is absorbed prior to said shaft so that said flexible member does not separate from said shaft.

108. The rivet of claim 100, wherein said leading end is at least in part conical.

109. The rivet of claim 108, wherein said leading end has a truncated leading portion.

110. The rivet of claim 100, including a plurality of said at least one projection.

111. The rivet of claim 110, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft.

112. The rivet of claim 110, wherein said projections are spaced apart from one another about the mid-longitudinal axis shaft.

113. The rivet of claim 110, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.

114. The rivet of claim 110, wherein said projections are oriented in at least two arrays around the mid-longitudinal axis of said shaft.
115. The rivet of claim 110, wherein said projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.
116. The rivet of claim 110, wherein said projections are positioned in a radially staggered configuration along said shaft.
117. The rivet of claim 110, wherein at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.
118. The rivet of claim 110, wherein said projections extend from said exterior surface along approximately one half the length of said shaft.
119. The rivet of claim 110, wherein said projections extend from said exterior surface along a portion of said shaft that is closer to said leading end of said shaft than said trailing end of said shaft.
120. The rivet of claim 110, wherein each of said projections is a fin.
121. The rivet of claim 120, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.
122. The rivet of claim 121, wherein said distal edge of said fin is curved.
123. The rivet of claim 110, wherein each of said projections is flexible.
124. The rivet of claim 123, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.
125. The rivet of claim 100, wherein said rivet comprises at least in part of a plastic material.
126. The rivet of claim 100, wherein said rivet comprises at least in part polyglycolic acid.
127. The rivet of claim 100, wherein said rivet comprises at least in part of a carbon composite.
128. The rivet of claim 100, wherein said rivet is at least in part bioabsorbable.
129. The rivet of claim 100, wherein said rivet comprises at least in part of a pliable material.
130. The rivet of claim 100, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.

131. The rivet of claim 100, wherein said trailing end of said shaft includes a depression configured to cooperatively engage a driver instrument.

132. The rivet of claim 131, wherein said depression is at least in part spherical.

133 The rivet of claim 100, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.

134. The combination of claim 133, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said passageway of said rivet.

135. The combination of claim 133, wherein said shaft of said driver has a length that is longer than the length of said rivet.

136. The combination of claim 133, wherein said shaft of said driver has a distal end with a sharp tip.

137. The combination of claim 136, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.

138. The combination of claim 133, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.

139. The rivet of claim 100, wherein said rivet has a length of approximately 8 mm.

140. The rivet of claim 100, wherein said shaft of said rivet has a diameter of approximately 2 mm.

141. The rivet of claim 100, wherein said flexible member has a diameter of approximately 2.5 mm.

142. The rivet of claim 102, wherein said passageway has a diameter of approximately 1.25 mm.

143. The rivet of claim 131, wherein said depression has a diameter of approximately 2 mm.

144. A tissue rivet for holding pieces of tissue together, said rivet comprising:

a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having an exterior surface with

at least one projection adapted to resist expulsion of said rivet from within the tissue; and

a flexible member proximate said trailing end of said shaft, said flexible member having a top and a bottom opposite said top, said bottom adapted to contact tissue upon insertion of said rivet into the tissue, at least a portion of said bottom forming an included angle relative to the mid-longitudinal axis of said shaft that is greater than 90 degrees.

145. The rivet of claim 144, wherein at least a second portion of said bottom of said flexible member forms an included angle relative to the mid-longitudinal axis of said shaft that is less than 90 degrees.

146. The rivet of claim 144, wherein said shaft is at least in part hollow.

147. The rivet of claim 144, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

148. The rivet of claim 144, wherein said top of said flexible member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said flexible member is in contact with the tissue.

149. The rivet of claim 144, wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

150. The rivet of claim 144, wherein said flexible member has a smaller mass than the mass of said shaft, whereby said flexible member is absorbed prior to said shaft so that said flexible member does not separate from said shaft.

151. The rivet of claim 144, wherein said leading end is at least in part conical.

152. The rivet of claim 144, including a plurality of said at least one projection.

153. The rivet of claim 152, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft.

154. The rivet of claim 152, wherein said projections are spaced apart from one another about the mid-longitudinal axis shaft.

155. The rivet of claim 152, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.

156. The rivet of claim 152, wherein said projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.
157. The rivet of claim 152, wherein said projections are positioned in a radially staggered configuration along said shaft.
158. The rivet of claim 152, wherein at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.
159. The rivet of claim 152, wherein each of said projections is a fin.
160. The rivet of claim 159, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.
161. The rivet of claim 160, wherein said distal edge of said fin is curved.
162. The rivet of claim 152, wherein each of said projections is flexible.
163. The rivet of claim 162, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.
164. The rivet of claim 144, wherein said rivet comprises at least in part polyglycolic acid.
165. The rivet of claim 144, wherein said rivet comprises at least in part of a carbon composite.
166. The rivet of claim 144, wherein said rivet is at least in part bioabsorbable.
167. The rivet of claim 144, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.
168 The rivet of claim 144, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.
169. The combination of claim 168, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said passageway of said rivet.
170. The combination of claim 168, wherein said shaft of said driver has a distal end with a sharp tip.
171. The combination of claim 170, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is

attached to said driver.

172. The combination of claim 168, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.

173. The rivet of claim 144, wherein said rivet has a length of approximately 8 mm.

174. The rivet of claim 144, wherein said shaft of said rivet has a diameter of approximately 2 mm.

175. The rivet of claim 144, wherein said flexible member has a diameter of approximately 2.5 mm.

176. A tissue rivet for holding pieces of tissue together, said rivet comprising:

a shaft having a leading end for insertion first into the tissue, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having an exterior surface with at least one projection adapted to resist expulsion of said rivet from within the tissue; and

a flexible member proximate said trailing end of said shaft, said flexible member having a top, a bottom opposite said top adapted to contact the tissue, and an outer perimeter between said top and said bottom, at least a portion of said outer perimeter being flexible relative to said shaft when said rivet is inserted into the tissue.

177. The rivet of claim 176, wherein said portion of said outer perimeter is moveable relative to said shaft between a first position where said portion of said perimeter forms an included angle that is generally perpendicular relative to the mid-longitudinal axis of said shaft and a second position where said portion of said perimeter forms an included angle that is obtuse relative to the mid-longitudinal axis of said shaft.

178. The rivet of claim 177, wherein said outer perimeter includes a second portion opposite said portion in a plane transverse to the mid-longitudinal axis of said shaft, said second portion forming an acute angle relative to the mid-longitudinal axis of said shaft in the second position.

179. The rivet of claim 176, wherein said outer perimeter of said flexible member and said at least one projection of said shaft are configured to maintain a compression force therebetween when said rivet is deployed in the tissue.

180. The rivet of claim 176, wherein the outer perimeter remains substantially in a single plane when moving relative to said shaft.
181. The rivet of claim 176, wherein said shaft is at least in part hollow.
182. The rivet of claim 176, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.
183. The rivet of claim 176, wherein said top of said flexible member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said flexible member is in contact with the tissue.
184. The rivet of claim 176, wherein said flexible member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.
185. The rivet of claim 176, wherein said flexible member has a smaller mass than the mass of said shaft, whereby said flexible member is absorbed prior to said shaft so that said flexible member does not separate from said shaft.
186. The rivet of claim 176, wherein said leading end is at least in part conical.
187. The rivet of claim 176, including a plurality of said at least one projection.
188. The rivet of claim 187, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft.
189. The rivet of claim 187, wherein said projections are spaced apart from one another about the mid-longitudinal axis shaft.
190. The rivet of claim 187, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.
191. The rivet of claim 187, wherein said projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.
192. The rivet of claim 187, wherein said projections are positioned in a radially staggered configuration along said shaft.
193. The rivet of claim 187, wherein at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.
194. The rivet of claim 187, wherein each of said projections is a fin.

195. The rivet of claim 194, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.
196. The rivet of claim 195, wherein said distal edge of said fin is curved.
197. The rivet of claim 187, wherein each of said projections is flexible.
198. The rivet of claim 197, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.
199. The rivet of claim 176, wherein said rivet comprises at least in part polyglycolic acid.
200. The rivet of claim 176, wherein said rivet comprises at least in part of a carbon composite.
201. The rivet of claim 176, wherein said rivet is at least in part bioabsorbable.
202. The rivet of claim 176, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.
203. The rivet of claim 176, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.
204. The combination of claim 203, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said passageway of said rivet.
205. The combination of claim 203, wherein said shaft of said driver has a distal end with a sharp tip.
206. The combination of claim 205, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.
207. The combination of claim 203, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.
208. The rivet of claim 176, wherein said rivet has a length of approximately 8 mm.
209. The rivet of claim 176, wherein said shaft of said rivet has a diameter of approximately 2 mm.

210. The rivet of claim 176, wherein said flexible member has a diameter of approximately 2.5 mm.

211. A tissue rivet for holding pieces of tissue together, said rivet comprising:

a shaft having a leading end, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having an exterior surface with at least one projection adapted to resist expulsion of said rivet from within the tissue; and

a member proximate said trailing end of said shaft, said member having a top, a bottom opposite said top, and an outer perimeter, said bottom adapted to contact tissue upon insertion of said rivet into the tissue, at least a first portion of said bottom adjacent to said outer perimeter being at an acute angle relative to the mid-longitudinal axis of said shaft, at least a second portion of said bottom adjacent to said outer perimeter being at an obtuse angle relative to the mid-longitudinal axis of said shaft.

212. The rivet of claim 211, wherein said shaft is at least in part hollow.

213. The rivet of claim 211, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

214. The rivet of claim 211, wherein said top of said member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said member is in contact with the tissue.

215. The rivet of claim 211, wherein said member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said member.

216. The rivet of claim 211, wherein said member has a smaller mass than the mass of said shaft, whereby said member is absorbed prior to said shaft so that said member does not separate from said shaft.

217. The rivet of claim 211, wherein said leading end is at least in part conical.

218. The rivet of claim 211, including a plurality of said at least one projection.

219. The rivet of claim 218, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft.

220. The rivet of claim 218, wherein said projections are spaced apart from one another about the mid-longitudinal axis shaft.

221. The rivet of claim 218, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.

222. The rivet of claim 218, wherein said projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.

223. The rivet of claim 218, wherein said projections are positioned in a radially staggered configuration along said shaft.

224. The rivet of claim 218, wherein at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.

225. The rivet of claim 218, wherein each of said projections is a fin.

226. The rivet of claim 225, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.

227. The rivet of claim 226, wherein said distal edge of said fin is curved.

228. The rivet of claim 218, wherein each of said projections is flexible.

229. The rivet of claim 228, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.

230. The rivet of claim 211, wherein said rivet comprises at least in part polyglycolic acid.

231. The rivet of claim 211, wherein said rivet comprises at least in part of a carbon composite.

232. The rivet of claim 211, wherein said rivet is at least in part bioabsorbable.

233. The rivet of claim 211, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.

234 The rivet of claim 211, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.

235. The combination of claim 234, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said

passageway of said rivet.

236. The combination of claim 234, wherein said shaft of said driver has a distal end with a sharp tip.

237. The combination of claim 236, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.

238. The combination of claim 234, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.

239. The rivet of claim 211, wherein said rivet has a length of approximately 8 mm.

240. The rivet of claim 211, wherein said shaft of said rivet has a diameter of approximately 2 mm.

241. The rivet of claim 211, wherein said flexible member has a diameter of approximately 2.5 mm.

242. A tissue rivet for holding pieces of tissue together, said rivet comprising:

a shaft having a leading end for insertion first into the tissue, a trailing end opposite said leading end, and a mid-longitudinal axis therebetween, said shaft having an exterior surface with at least one projection adapted to resist expulsion of said rivet from within the tissue; and

a member proximate said trailing end of said shaft, said member having a top and a bottom opposite said top, said bottom being adapted to contact tissue, at least a portion of said member being moveable relative to said shaft between an undeployed position where said bottom surface is not in contact with the tissue and a deployed position where said bottom surface contacts the tissue, said member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape.

243. The rivet of claim 242, wherein said shaft is at least in part hollow.

244. The rivet of claim 242, wherein said shaft includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft.

245. The rivet of claim 242, wherein said top of said member is deformable to have an at least in part concave shape when said rivet is inserted into the tissue and said

member is in contact with the tissue.

246. The rivet of claim 242, wherein said member has a greater surface area to mass ratio than said shaft for permitting a higher absorption rate of said bioabsorbable material of said member.

247. The rivet of claim 242, wherein said member has a smaller mass than the mass of said shaft, whereby said member is absorbed prior to said shaft so that said member does not separate from said shaft.

248. The rivet of claim 242, wherein said leading end is at least in part conical.

249. The rivet of claim 242, including a plurality of said at least one projection.

250. The rivet of claim 249, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft.

251. The rivet of claim 249, wherein said projections are spaced apart from one another about the mid-longitudinal axis shaft.

252. The rivet of claim 249, wherein said projections are spaced apart from one another along the mid-longitudinal axis of said shaft and about the mid-longitudinal axis of said shaft.

253. The rivet of claim 249, wherein said projections are oriented in at least four arrays around the mid-longitudinal axis of said shaft.

254. The rivet of claim 249, wherein said projections are positioned in a radially staggered configuration along said shaft.

255. The rivet of claim 249, wherein at least two of said projections extend from said shaft in a same plane transverse to the mid-longitudinal axis of said shaft.

256. The rivet of claim 249, wherein each of said projections is a fin.

257. The rivet of claim 256, wherein each fin has two sides and a distal edge oriented away from the mid-longitudinal axis of said shaft.

258. The rivet of claim 257, wherein said distal edge of said fin is curved.

259. The rivet of claim 249, wherein each of said projections is flexible.

260. The rivet of claim 259, wherein said flexible projections are adapted to flex towards said shaft as said rivet is being inserted into the tissue.

261. The rivet of claim 242, wherein said rivet comprises at least in part polyglycolic acid.

262. The rivet of claim 242, wherein said rivet comprises at least in part of a carbon composite.

263. The rivet of claim 242, wherein said rivet is at least in part bioabsorbable.

264. The rivet of claim 242, wherein said trailing end of said shaft is configured to cooperatively engage a driver instrument.

265 The rivet of claim 242, in combination with a driver configured to insert said rivet into the tissue, said driver having a handle and a shaft extending from said handle.

266. The combination of claim 265, wherein said shaft of said rivet includes a passageway from said trailing end to said leading end along the mid-longitudinal axis of said shaft, said shaft of said driver being adapted to pass through said passageway of said rivet.

267. The combination of claim 265, wherein said shaft of said driver has a distal end with a sharp tip.

268. The combination of claim 267, wherein said tip is adapted to extend at least 4 mm beyond said leading end of said shaft of said rivet when said rivet is attached to said driver.

269. The combination of claim 265, wherein said driver has a projection that is adapted to cooperatively engage said trailing end of said shaft of said rivet.

270. The rivet of claim 242, wherein said rivet has a length of approximately 8 mm.

271. The rivet of claim 242, wherein said shaft of said rivet has a diameter of approximately 2 mm.

272. The rivet of claim 242, wherein said flexible member has a diameter of approximately 2.5 mm.

273. A method for holding pieces of tissue together with a tissue rivet, the method comprising the steps of:

providing the rivet having a shaft with a leading end for insertion first into the tissue, a trailing end opposite the leading end, a mid-longitudinal axis therebetween, and a member proximate the trailing end of the shaft, the member having a top, a bottom opposite the top, the bottom being adapted to contact tissue, at least a portion of the member being moveable relative to the shaft

between an undeployed position where the bottom surface is not in contact with the tissue and a deployed position where the bottom surface contacts the tissue, the member having a first shape in the deployed position and a second shape in the undeployed position, the first shape being different from the second shape;

inserting the rivet into the tissue until the bottom contacts the tissue; and

moving at least a portion of the member relative to the shaft to the deployed position.

274. The method of claim 273, wherein the member forms an included angle relative to the mid-longitudinal axis of the shaft of said rivet that is greater than 90 degrees.

275. The method of claim 273, wherein the member forms an included angle relative to the mid-longitudinal axis of the shaft of said rivet that is less than 90 degrees.

276. The method of claim 273, further comprising the step of engaging a driving instrument to the rivet.

277. The method of claim 276, wherein the rivet has a passageway between the leading and trailing ends of the shaft and the driving instrument includes a handle, a shaft extending from the handle, and a face at a junction of the handle and the shaft of the driving instrument, the step of engaging including inserting the shaft of the driving instrument into the passageway until the face of the driving instrument contacts the top of the member.

278. The method of claim 276, wherein the step of engaging the driving instrument with the rivet is performed so that the driving instrument does not contact the bottom of the flexible member.

279. The method of claim 273, wherein the step of inserting includes pushing the rivet into the tissue.

280. The method of claim 273, wherein the step of inserting includes inserting the rivet into a portion of a meniscus of a human knee.

281. The method of claim 280, wherein the step of inserting includes inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee.

282. The method of claim 273, wherein the shaft has an exterior surface with at least one projection adapted to resist expulsion of the rivet from within the tissue, further comprising the step of compressing the pieces of tissue together between the at least one projection and the flexible member.

283. A method for holding pieces of tissue together with a tissue rivet, the method comprising the steps of:

providing the rivet having a shaft with a leading end for insertion first into the tissue, a trailing end opposite the leading end, and a flexible member proximate the trailing end of the shaft, the flexible member having a top and a bottom opposite the top;

engaging a driving instrument to the rivet; and

inserting the rivet into the tissue until the bottom of the flexible member contacts the tissue and the flexible member deforms to conform to the curvature of the tissue adjacent the rivet.

284. The method of claim 283, wherein the flexible member forms an included angle relative to the mid-longitudinal axis of the shaft of said rivet that is greater than 90 degrees.

285. The method of claim 283, wherein the flexible member forms an included angle relative to the mid-longitudinal axis of the shaft of said rivet that is less than 90 degrees.

286. The method of claim 283, wherein the rivet has a passageway between the leading and trailing ends of the shaft and the driving instrument includes a handle, a shaft extending from the handle, and a face at a junction of the handle and the shaft of the driving instrument, the step of engaging including inserting the shaft of the driving instrument into the passageway until the face of the driving instrument contacts the top of the flexible member.

287. The method of claim 286, wherein the step of engaging the driving instrument with the rivet is performed so that the driving instrument does not contact the bottom of the flexible member.

288. The method of claim 283, wherein the step of engaging includes snap-fitting the rivet onto a portion of the driving instrument.

289. The method of claim 283, wherein the step of inserting includes pushing the rivet into the tissue.

290. The method of claim 283, wherein the step of inserting includes inserting the rivet into a portion of a meniscus of a human knee.

291. The method of claim 290, wherein the step of inserting includes inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee.

292. The method of claim 283, wherein the shaft has an exterior surface with at least one projection adapted to resist expulsion of the rivet from within the tissue, further comprising the step of compressing the pieces of tissue together between the at least one projection and the flexible member.

293. A method for holding pieces of tissue together with a tissue rivet, the method comprising the steps of:

providing the tissue rivet having a shaft with a leading end for insertion first into the tissue, a trailing end opposite the leading end, and a member proximate the trailing end of the shaft, the member having a top, a bottom opposite the top, and an outer perimeter; and

inserting the rivet into the tissue until the bottom of the member contacts the tissue, at least a first portion of the bottom adjacent to the outer perimeter of the member being at an acute angle relative to the mid-longitudinal axis of the shaft, at least a second portion of the bottom adjacent to the outer perimeter of the member being at an obtuse angle relative to the mid-longitudinal axis of the shaft.

294. The method of claim 293, further comprising the step of engaging a driving instrument to the rivet.

295. The method of claim 294, wherein the rivet has a passageway between the leading and trailing ends of the shaft and the driving instrument includes a handle, a shaft extending from the handle, and a face at a junction of the handle and the shaft of the driving instrument, the step of engaging including inserting the shaft of the driving instrument into the passageway until the face of the driving instrument contacts the top of the member.

296. The method of claim 294, wherein the step of engaging the driving instrument with the rivet is performed so that the driving instrument does not contact the bottom of the flexible member.

297. The method of claim 293, wherein the step of inserting includes pushing the rivet into the tissue.

298. The method of claim 293, wherein the step of inserting includes inserting the rivet into a portion of a meniscus of a human knee.

299. The method of claim 298, wherein the step of inserting includes inserting the leading end of the shaft into the meniscus in a direction away from the center of the knee.

300. The method of claim 293, wherein the shaft has an exterior surface with at least one projection adapted to resist expulsion of the rivet from within the tissue, further comprising the step of compressing the pieces of tissue together between the at least one projection and the flexible member.

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EVIDENCE APPENDIX

Attached hereto are Exhibits A to F, which appear in the record as part of the September 2004 Amendment. Current Exhibits A to F correspond to Exhibits A, B, E, F, D, and H, respectively, of the September 2004 Amendment.